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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/620,820	07/21/2000	Alan D. Attie	960296.97290	4397

7590 07/28/2004

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/620,820

Applicant(s)

ATTIE ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-17 are pending in the application. Claims 13-16 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-12 and 17 are currently under examination.

This Office Action is in response to the amendment filed on 6/18/04.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/18/04 has been entered.

Response to Amendment

The rejection of claims 1-12 and 17 under 35 U.S.C. 112 1st paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1-12 and 17 under 35 U.S.C. 103 (a) is maintained for reasons set forth of the record mailed on 12/17/03 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Twisk et al., in view of Teasdale and Jackson and Attie et al. (5,521,071).

In response to this rejection, Applicants argue that the combination of elements recited by the present claim in fact results in a lowering of serum cholesterol, which is not fairly predictable from prior art. The combined teaching of the cited references does not provide sufficient evidence for reasonable expectation of the success of the claimed invention because of the complex nature of biological system of cholesterol secretion and the uncertainty arising in general with techniques of genetic engineering. Applicants allege that the rejection is an "obvious to try" rejection because the cited art does not make it clear that the claimed process would actually lower serum cholesterol. Applicants thus conclude the claimed invention is not obvious in view of the cited art.

These arguments have been fully considered but deemed unpersuasive. The teachings of Twisk et al., Teasdale and Jackson, and Attie et al. were discussed in detail in the Office Action mailed on 3/25/03 and 12/17/03. The reasons for the obviousness of this rejection have also been discussed in detail in these Office Actions. Briefly, based on the teaching of Twisk et al., it would have been obvious to one of ordinary skill of art who intend to lower serum cholesterol in a patient to decrease apoB secretion, thus lower LDL synthesis. Although the processing and secretion of cholesterol is a complex area, the mechanisms involved in this process is extensively studied and it is clear that lowering LDL synthesis would lower serum cholesterol. Applicants' argument about LDL receptor not only regulates apoB secretion but also reabsorption is well taken. However, this notion does not in anyway affect the reasonable expectation of success for using the soluble LDL receptor with ER localization signal to enhance pre-secretory degradation

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of apoB, which has been demonstrated by Twisk et al (see Figure 5, and page 527, 1st col., 3rd and 4th paragraph). LDL receptor mediated reabsorption also decreases apoB circulation, thus decreases LDL synthesis and lowering serum cholesterol. In response to the uncertainty arising from genetic engineering, Twisk et al. has demonstrated the use of an adenoviral vector encoding LDL receptor for the delivery of said gene to hepatocytes (see page 524, 1st col., 1st paragraph). Absent evidence from the contrary, one of ordinary skill in the art would have reasonable expectation of success for using a soluble LDL receptor with ER retaining signal to achieve lowering of serum cholesterol. Therefore, the claimed invention would have been obvious in view of the teaching of the cited art, and this rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Celine Qian, Ph.D.

A handwritten signature in black ink, appearing to read 'Celine Qian', with a long horizontal stroke extending to the right.